HFA-305

Date of Approval:

JUN 8 2004

# FREEDOM OF INFORMATION SUMMARY

**Original Abbreviated New Animal Drug Application** 

200-273

**VETRO-GEN** Veterinary Ophthalmic Ointment (gentamicin sulfate)

**Dogs and Cats** 

It is indicated for topical treatment of conjunctivitis caused by susceptible bacteria in dogs and cats.

Sponsored by: Altana Inc. Melville, NY 11747

## FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

File Number: ANADA 200-273 a.

Altana Inc. b. Sponsor: 60 Baylis Rd.

Melville, NY 11747

Labeler Code: 025463

Established Name: Gentamicin sulfate

VETRO-GEN Veterinary Ophthalmic Proprietary Name:

**Ointment** 

Dosage Form: Topical ointment

How Supplied: 3.5 gram (1/8 oz) tubes f.

g. How Dispensed: Rx

h. Amount of Active Each gram contains: gentamicin sulfate

Ingredients: (equivalent to 3 mg gentamicin) in a base

of mineral oil and white petrolatum. i. Route of

Administration: Topical

k. Recommended

j. Species/Class: Dogs and cats

Apply approximately ½ inch strip of Dosage:

> VETRO-GEN Veterinary Ophthalmic Ointment to the affected eye(s) 2 to 4 times

a day.

1. Pharmacological

Category:

Antibacterial

m. Indications: VETRO-GEN Veterinary Ophthalmic

Ointment is indicated for topical treatment of conjunctivitis caused by susceptible

bacteria in dogs and cats.

n. Pioneer Product: GENTOCIN Ophthalmic Ointment;

gentamicin sulfate; NADA 98-989 Schering-Plough Animal Health

## 2. Target Animal Safety and Drug Effectiveness:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and drug effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based upon the formulation characteristics of the generic product, Pharmaderm, Veterinary Division of Altana Inc. was granted a waiver from the requirement for *in vivo* bioequivalence study for VETRO-GEN Veterinary Ophthalmic Ointment (gentamicin sulfate). The generic product is administered as a topical ointment, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, GENTOCIN Ophthalmic Ointment (gentamicin sulfate), the subject of Schering Plough Animal Health's NADA 98-989, was approved on April 2, 1976.

### 3. HUMAN SAFETY:

This drug is indicated for use in dogs and cats, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this ANADA.

Human Warning is provided on the product label as follows: "Keep out of reach of children"

## 4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that VETRO-GEN Veterinary Ophthalmic Ointment, when used under its proposed conditions of use, is safe and effective for its labeled indications.

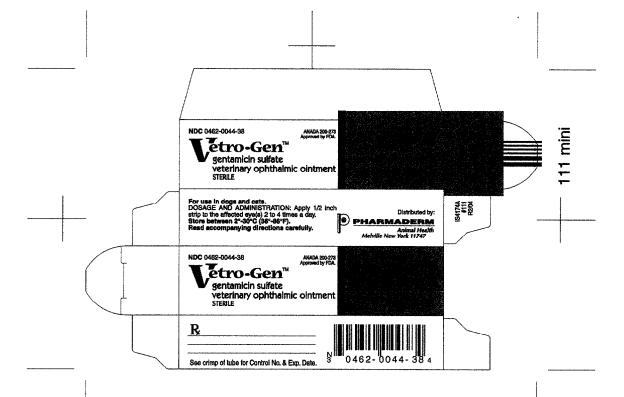
## 5. ATTACHMENTS:

Facsimile Generic Labeling and Currently Approved Pioneer Labeling are attached as indicted below:

## Generic Labeling for ANADA 200-273

VETRO-GEN Veterinary Ophthalmic Ointment- 3.5 gram (1/8 oz) tube, box and Insert

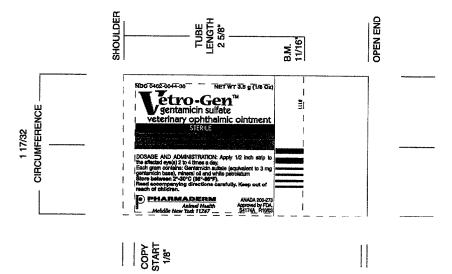
<u>Pioneer Labeling for NADA 98-989:</u> GENTOCIN Ophthalmic Ointment- 1/8 oz. tube, box and Insert



Item #: IS4174A Die Size: .750" x .6250" x 2.8437" Pharma #: 111mini PLACED PMS: 1795, Black

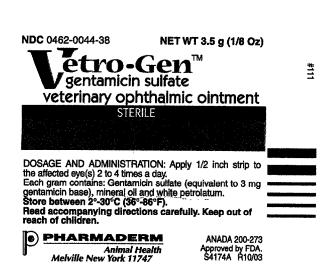
 $\Box$ 

100%



Item #: S4174A Die Size: 2 5/8 x 1 17/32 Pharma #: 111 PMS: 1795, Black

175%





# veterinary ophthalmic ointment

#### STERILE

For use in dogs and cats.

**DESCRIPTION:** Gentamicin sulfate is a water soluble antibiotic of the aminoglycoside group active against a wide variety of pathogenic gram-negative and gram-positive bacteria.

Vetro-Gen™ Ophthalmic Ointment is a sterile ointment, each gram containing gentamicin sulfate (equivalent to 3 mg gentamicin) in a base of mineral oil and white petrolatum.

CHEMISTRY: Gentamicin sulfate is an aminoglycoside antibiotic mixture derived from Micromonospora purpurea of the Actinomycetes group. It is a powder, white to buff in color, readily soluble in water, and heat stable.

ACTION: Gentamicin sulfate, a broad spectrum antibiotic, is a highly effective topical treatment in primary and secondary bacterial infections of the eye and surrounding tissues. Gentamicin is bactericidal in vitro against a wide variety of gram-positive and gram-negative bacteria. Concentrations of gentamicin sulfate required to inhibit growth of gram-positive and gram-negative clinical and laboratory strains of bacteria tested were less than those of neomycin in most instances.12 Gentamicin is active against most gram-negative bacteria including Pseudomonas aeruginosa, indole positive and negative Proteus species, Escherichia coli, Klebsiella sp. and Enterobacter sp. Gentamicin is also active against (over)

strains of gram-positive bacteria including Staphylococcus species and Streptococcus species.

INDICATIONS: Vetro-Gen™ Ophthalmic Ointment is indicated for topical treatment of conjunctivitis caused by susceptible bacteria in dogs and cats.

**DOSAGE AND ADMINISTRATION:** Apply approximately 1/2 inch strip of Vetro-Gen™ Ophthalmic Ointment to the affected eye(s) 2 to 4 times a day.

PRECAUTIONS: Antibiotic susceptibility of infecting organisms should be determined prior to the use of these preparations. Prolonged use of topical antibiotics may give rise to overgrowth of nonsusceptible organisms such as fungi. Should this occur or if irritation or hypersensitivity to any component develops, discontinue use of the preparation and institute appropriate therapy. Ophthalmic ointments may retard corneal healing.

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

HOW SUPPLIED: Vetro-Gen™ veterinary Ophthalmic Ointment is supplied in 3.5 a (1/8 Oz) sterile tamperproof tubes.

NDC 0462-0044-38

3.5 gram tube

#### Store between 2°-30°C (36°-86°F).

1. Weinstein MJ, Leudemann GM, Oden EM, Wagman GH. Gentamicin, a new broad spectrum antibiotic complex. Antimicrob. Agents and Chemother. 1963:1-7, 2. Black J, et al. Pharmacology of Gentamicin: a new

broad spectrum antibiotic. Antimicrob. Agents and Chemother. 1964:138-147.

Distributed by:



114438A #111 R2/04



Item #I14438A Die size 3.25 x 5 Pharma #111 actual Black & PMS 1795

98-989# 4-30-02

13347654

PRODUCT INFORMATION

# Gentocin® Ophthalmic Solution—Sterile (GENTAMICIN SULFATE)

NADA #99-008, Approved by FDA.

# Gentocin<sup>®</sup> Ophthalmic Ointment—Sterile (GENTAMICIN SULFATE)

NADA #98-989, Approved by FDA.

## Veterinary For Use in Dogs and Cats

**DESCRIPTION:** Gentamicin sulfate is a water soluble antibiotic of the aminoglycoside group active against a wide variety of pathogenic gram-negative and gram-positive bacteria.

GENTOCIN Ophthalmic Solution is a sterile aqueous solution buffered to approximately pH 7 for use in the eye. Each mL contains gentamicin sulfate equivalent to 3 mg gentamicin, 2.9 mg disodium phosphate, 0.1 mg monosodium phosphate, 7.4 mg sodium chloride, 0.1 mg benzalkonium chloride as preservative, and purified water q.s.

GENTOCIN Ophthalmic Ointment is a sterile ointment, each gram containing gentamicin sulfate equivalent to 3 mg gentamicin with 0.5 mg methylparaben and 0.1 mg propylparaben as preservatives in a bland base of white petrolatum. CHEMISTRY: Gentamicin is an aminoglycoside antibiotic mixture derived from Micromonospora purpurea of the Actinomycetes group. It is a powder, white to buff in color, readily soluble in water, and heat stable.

ACTION: Gentamicin sulfate, a broad-spectrum antibiotic, is a highly effective topical treatment in primary and secondary bacterial infections of the eye and surrounding tissues. Gentamicin is bactericidal in vitro against a wide variety of gram-positive and gram-negative bacteria. Concentrations of gentamicin sulfate required to inhibit growth of gram-positive and gram-negative clinical and laboratory strains of bacteria tested were less than those of neomycin in most instances. 1.2 Gentamicin is active against most gram-negative bacteria including Pseudomonas aeruginosa, indole positive and negative Proteus species, Escherichia coli, Klebsiella sp.

and Enterobacter sp. Gentamicin is also active against strains of gram-positive bacteria including Staphylococcus species and Streptococcus species.

INDICATIONS: GENTOCIN Ophthalmic Solution and Ointment are indicated for topical treatment of conjunctivitis caused by susceptible bacteria in dogs and cats.

DOSAGE AND ADMINISTRATION: GENTOCIN Ophthalmic Solution—1 or 2 drops instilled into the conjuctival sac 2 to 4 times a day. GENTOCIN Ophthalmic Ointment—apply approximately ½-inch strip to the affected eye 2 to 4 times a day.

PRECAUTIONS: Antibiotic susceptibility of infecting organisms should be determined prior to the use of these preparations. Prolonged use of topical antibiotics may give rise to overgrowth of nonsusceptible organisms such as fungi. Should this occur or if irritation or hypersensitivity to any component develops, discontinue use of the preparation and institute appropriate therapy. Ophthalmic ointments may retard corneal healing.

**CAUTION:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**HOW SUPPLIED:** GENTOCIN Ophthalmic Solution—Sterile—5 mL plastic dropper bottle, box of 12, NDC 0061-0702-05.

GENTOCIN Ophthalmic Ointment—Sterile—¼ oz. tube, box of 12, NDC 0061-0447-05.

Store Solution and Ointment between 2° and 30°C (36° and 86°F).

#### REFERENCES

1. Weinstein MJ, Leudemann GM, Oden EM, Wagman GH. Gentamicin, a new broad spectrum antibiotic complex. Antimicrob Agents and Chemother.

 Black J, et al. Pharmacology of Gentamicin: a new broad spectrum antibiotic. Antimicrob Agents and Chemother. 1964:138-147.

January 1999

Schering-Plough Animal Health Corp. Union, New Jersey 07083

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#### Must be sold in unbroken packages only.

Veterinary Ophthalmic Ointment (GENTAMICIN SULFATE)

Sterile

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1/8 onuce Each 12 Tubes

For use in dogs and cats.

Each gram contains: gentamicin sulfate equivalent to 3 mg gentamicin with 0.5 mg methylparaben and 0.1 mg propylparaben as preservatives in a bland base of petrolatum

Usual dose: Apply 1/2 inch strip to affected eye 2 to 4 times a day.

Read accompanying directions carefully.

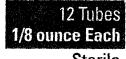
Store between 2° and 30°C (36° and 86°F).

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13520631 Rev 4/96

Gentocin® (GENTAMICIN SULFATE) **Ophthalmic Ointment** Veterinary For use in dogs and cats.

LOT EXP NDC 0061-0447-05



Sterile

# Gentocin® (GENTAMICIN SULFATE) **Ophthalmic Ointment** Veterinary

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

NADA #98-989, Approved by FDA.

Schering-Plough Animal Health

**Gentocin®** (GENTAMICIN SULFATE) **Ophthalmic Ointment** Veterinary

For use in dogs and cats.

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